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GENERAL ELECTRIC COMPANY and  
GE HEALTHCARE INC.

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION**

WILLIAM PASCHAL and  
PATRICIA PASCHAL,

Plaintiffs,

v.

BAYER HEALTHCARE  
PHARMACEUTICALS, INC.;  
BAYER HEALTHCARE LLC;  
GENERAL ELECTRIC  
COMPANY; GE HEALTHCARE,  
INC.; COVIDIEN, INC.;  
MALLINCKRODT, INC.; and  
BRACCO DIAGNOSTICS, INC.,

Defendants.

Case No. 3:08-cv-01298 EMC

**DEFENDANTS GENERAL  
ELECTRIC COMPANY'S AND GE  
HEALTHCARE INC.'S ANSWER  
AND AFFIRMATIVE DEFENSES**

**[Jury Trial Demanded]**

Defendants GENERAL ELECTRIC COMPANY and GE HEALTHCARE INC. (incorrectly sued as GE Healthcare, Inc.) ("Defendants") respectfully file this Answer to Plaintiffs' Original Complaint and Demand for Jury Trial ("Complaint"), and respond as follows:

**NATURE OF THE CASE**

1. Defendants admit that NSF is a rare, acquired systemic disease which may lead to the increased formation of connective tissue in the skin, causing it to

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ANSWER AND AFFIRMATIVE DEFENSES

CASE NO. 3:08-CV-01298 EMC

1 become thickened, coarse, and hard, leading to disabling contractures. NSF is  
2 progressive and may be fatal. Defendants admit that Omniscan™ is a gadolinium-  
3 based contrast agent that is FDA approved for use in the United States in MRI  
4 procedures. Defendants further admit that Omniscan™ is approved by the FDA as  
5 reasonably safe for its approved uses when utilized properly, in conjunction with  
6 the medical judgment of a trained healthcare professional and in accordance with its  
7 accompanying warnings, instructions, and contraindications. Defendants expressly  
8 deny Paragraph 1 to the extent it purports to expand, or alter the meaning of, or is  
9 otherwise inconsistent with the accepted medical and scientific definition of  
10 Nephrogenic Systemic Fibrosis also known as Nephrogenic Fibrosing Dermopathy.  
11 Except as admitted, Defendants are without knowledge or information sufficient to  
12 form a belief as to the truth of the allegations contained in Paragraph 1 and  
13 therefore deny the same.

#### 14 **JURISDICTION AND VENUE**

15 2. Paragraph 2 contains legal conclusions to which no response is  
16 required. To the extent a response is deemed to be required, Defendants admit that  
17 pursuant to 28 U.S.C. § 1332, GE Healthcare Inc. is considered a citizen of both the  
18 State of Delaware and the State of New Jersey. Defendants admit that pursuant to  
19 28 U.S.C. § 1332, General Electric Company is considered a citizen of both the  
20 State of New York and the State of Connecticut. Defendants further admit that  
21 General Electric Company and GE Healthcare Inc. conduct business in the state of  
22 California. Except as admitted, Defendants are without knowledge or information  
23 sufficient to form a belief as to the truth of the allegations contained in Paragraph 2  
24 and therefore deny the same.

#### 25 **INTRADISTRICT ASSIGNMENT**

26 3. Defendants are without knowledge or information sufficient to form a  
27 belief as to the truth of the allegations contained in Paragraph 3 and therefore deny  
28 the same.

**PARTIES**

***Plaintiffs***

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 and therefore deny the same.

***Defendants***

5. Paragraph 5 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 and therefore deny the same.

6. Paragraph 6 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6 and therefore deny the same.

7. Paragraph 7 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 and therefore deny the same.

8. Paragraph 8 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 and therefore deny the same.

9. Defendants admit that GE Healthcare Inc. distributes, sells, and markets Omniscan™ in the United States in accordance with FDA rules and regulations. Except as admitted, Defendants deny the allegations contained in Paragraph 9.

10. Defendants admit that General Electric Company is a New York corporation, with its principal place of business at 3135 Easton Turnpike, Fairfield,

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1 Connecticut 06828. Except as admitted, Defendants deny the allegations contained  
2 in Paragraph 10.

3 11. Defendants admit that GE Healthcare Inc. is a Delaware corporation,  
4 with its principal place of business at 101 Carnegie Center, Princeton, New Jersey,  
5 08540. Except as admitted, Defendants deny the allegations contained in Paragraph  
6 11.

7 12. Defendants admit that GE Healthcare Inc. distributes, sells, and  
8 markets Omniscan™ in the United States in accordance with FDA rules and  
9 regulations. Except as admitted, Defendants deny the allegations contained in  
10 Paragraph 12.

11 13. Paragraph 13 is directed to another defendant and thus requires no  
12 response. In the alternative, Defendants are without knowledge or information  
13 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
14 13 and therefore deny the same.

15 14. Paragraph 14 is directed to another defendant and thus requires no  
16 response. In the alternative, Defendants are without knowledge or information  
17 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
18 14 and therefore deny the same.

19 15. Paragraph 15 is directed to another defendant and thus requires no  
20 response. In the alternative, Defendants are without knowledge or information  
21 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
22 15 and therefore deny the same.

23 16. Paragraph 16 is directed to another defendant and thus requires no  
24 response. In the alternative, Defendants are without knowledge or information  
25 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
26 16 and therefore deny the same.

27 17. Paragraph 17 is directed to another defendant and thus requires no  
28 response. In the alternative, Defendants are without knowledge or information

1 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
2 17 and therefore deny the same.

3 18. Paragraph 18 is directed to another defendant and thus requires no  
4 response. In the alternative, Defendants are without knowledge or information  
5 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
6 18 and therefore deny the same.

7 19. Paragraph 19 is directed to another defendant and thus requires no  
8 response. In the alternative, Defendants are without knowledge or information  
9 sufficient to form a belief as to the truth of the allegations contained in Paragraph  
10 19 and therefore deny the same.

11 20. Defendants are without knowledge or information sufficient to form a  
12 belief as to the truth of the allegations contained in Paragraph 20 and therefore deny  
13 the same.

14 **FACTS**

15 21. Defendants are without knowledge or information sufficient to form a  
16 belief as to the truth of the allegations contained in Paragraph 21 and therefore deny  
17 the same.

18 22. Defendants admit that NSF/NFD is a rare, acquired systemic disease  
19 which may lead to the increased formation of connective tissue in the skin, causing  
20 it to become thickened, coarse, and hard, leading to disabling contractures. NSF is  
21 progressive and may be fatal. Defendants expressly deny Paragraph 22 to the  
22 extent it purports to expand, or alter the meaning of, or is otherwise inconsistent  
23 with the accepted medical and scientific definition of Nephrogenic Systemic  
24 Fibrosis also known as Nephrogenic Fibrosing Dermopathy. Except as admitted,  
25 Defendants deny the allegations contained in Paragraph 22.

26 23. Defendants deny the allegations contained in Paragraph 23.

27 ///

28 ///

1           24. Defendants admit that gadolinium is not an endogenous metal in the  
2 human body. Except as admitted, Defendants deny the allegations contained in  
3 Paragraph 24.

4           25. Paragraph 25 contains scientific conclusions and opinions that are  
5 more properly the subject of expert opinion testimony. To the extent that a  
6 response to Paragraph 25 is deemed to be required, Defendants admit that  
7 Omniscan™ utilizes a chelated formulation to bind gadolinium ions. Except as  
8 admitted, Defendants deny the allegations contained in Paragraph 25.

9           26. Paragraph 26 contains scientific conclusions and opinions that are  
10 more properly the subject of expert opinion testimony. To the extent that a  
11 response to Paragraph 26 is deemed to be required, Defendants admit that  
12 Omniscan™ utilizes a chelated formulation to bind gadolinium ions. Defendants  
13 admit that chelating gadolinium facilitates excretion of the complex through the  
14 kidneys. Except as admitted, Defendants deny the allegations contained in  
15 Paragraph 26.

16           27. Defendants are without knowledge or information sufficient to form a  
17 belief as to the truth of the allegations contained in Paragraph 27 and therefore deny  
18 the same.

19           28. Defendants deny the allegations contained in Paragraph 28.

20           29. Paragraph 29 contains scientific conclusions and opinions that are  
21 more properly the subject of expert opinion testimony. In the alternative,  
22 Defendants admit that NSF was first reported in medical literature in 2000,  
23 retrospectively referencing a case from 1997. Defendants further admit that the  
24 first report of a case of NSF associated with the administration of a gadolinium-  
25 based contrast agent appeared in the medical literature in March 2006. Except as  
26 admitted, Defendants are without knowledge or information sufficient to form a  
27 belief as to the truth of the allegations contained in Paragraph 29 and therefore deny  
28 the same.



1           30. Defendants are without knowledge or information sufficient to form a  
2 belief as to the truth of the allegations contained in Paragraph 30 and therefore deny  
3 the same.

4           31. Defendants are without knowledge or information sufficient to form a  
5 belief as to the truth of the allegations contained in Paragraph 31 and therefore deny  
6 the same.

7           32. Defendants deny the allegations contained in Paragraph 32.

8           33. Defendants deny the allegations contained in Paragraph 33.

9           34. Defendants deny the allegations contained in Paragraph 34.

10          35. Defendants deny the allegations contained in Paragraph 35.

11          36. Defendants admit that GE Healthcare Inc. distributes, sells and  
12 markets Omniscan™ in the United States in accordance with FDA rules and  
13 regulations. Omniscan™ is approved by the FDA as reasonably safe for its  
14 approved uses when utilized properly, in conjunction with the medical judgment of  
15 a trained healthcare professional and in accordance with its accompanying  
16 warnings, instructions and contraindications. In June and December 2006,  
17 Defendant GE Healthcare Inc. issued "Dear Healthcare Professional" letters in the  
18 United States regarding NSF. In May 2007, the FDA issued a notice that labeling  
19 for all gadolinium-based contrast agents should include a boxed warning. To the  
20 extent the allegations in Paragraph 36 are directed to other defendants, General  
21 Electric Company and GE Healthcare Inc. are without knowledge or information  
22 sufficient to form a belief as to the truth of the allegations and therefore deny the  
23 same. Defendants deny any remaining allegations contained in Paragraph 36.

24          37. Defendants deny the allegations contained in Paragraph 37.

25          38. Defendants deny the allegations contained in Paragraph 38.

26          39. Defendants deny the allegations contained in Paragraph 39.

27          40. Defendants deny the allegations contained in Paragraph 40.

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**DISCOVERY RULE & FRAUDULENT CONCEALMENT**

41. Paragraph 41 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 41.

42. Paragraph 42 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 42.

**FIRST CAUSE OF ACTION**

**STRICT LIABILITY: FAILURE TO WARN**

43. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 43 as if set forth fully herein.

44. Defendants deny the allegations contained in Paragraph 44.

45. Paragraph 45 contains legal conclusions to which no response is required. Paragraph 45 further contains scientific conclusions and opinions that are more properly the subject of expert testimony. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraph 45.

**SECOND CAUSE OF ACTION**

**STRICT LIABILITY: DESIGN DEFECT**

46. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 45 as if set forth fully herein.

47. Defendants admit that GE Healthcare Inc. distributes, sells and markets Omniscan™ in the United States in accordance with FDA rules and regulations. Defendants further admit that General Electric Company manufactures magnetic resonance machines. Except as admitted, Defendants deny the allegations contained in Paragraph 47.

48. Defendants deny the allegations contained in Paragraph 48.

49. Defendants deny the allegations contained in Paragraph 49.

50. Defendants deny the allegations contained in Paragraph 50.



**THIRD CAUSE OF ACTION**

**STRICT LIABILITY: FAILURE TO ADEQUATELY TEST**

51. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 50 as if set forth fully herein.

52. Defendants admit that GE Healthcare Inc. distributes, markets and sells Omniscan™ in accordance with FDA rules and regulations. Omniscan™ is approved by the FDA as reasonably safe for its approved uses when utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Defendants affirmatively state that Omniscan™ is not distributed, marketed or sold directly to consumers or the general public. Except as admitted, Defendants deny the allegations contained in Paragraph 52.

53. Defendants deny the allegations contained in Paragraph 53.

54. Defendants deny the allegations contained in Paragraph 54.

**FOURTH CAUSE OF ACTION**

**NEGLIGENCE**

55. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 54 as if set forth fully herein.

56. Paragraph 56 contains legal conclusions to which no response is required. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraph 56.

57. Defendants deny the allegations contained in Paragraph 57.

58. Defendants deny the allegations contained in Paragraph 58.

59. Defendants deny the allegations contained in Paragraph 59.

60. Defendants deny the allegations contained in Paragraph 60.

61. Defendants deny the allegations contained in Paragraph 61.

62. Defendants deny the allegations contained in Paragraph 62.

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**FIFTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**

63. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 62 as if set forth fully herein.

64. Defendants deny the allegations contained in Paragraph 64.

65. Defendants admit that Omniscan™ is approved by the FDA as reasonably safe for its approved uses when utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Except as admitted, Defendants deny the allegations contained in Paragraph 65.

66. Defendants deny the allegations contained in Paragraph 66.

67. Defendants deny the allegations contained in Paragraph 67.

68. Defendants deny the allegations contained in Paragraph 68.

**SIXTH CAUSE OF ACTION**

**FRAUD**

69. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 68 as if set forth fully herein.

70. Defendants deny the allegations contained in Paragraph 70.

71. Defendants deny the allegations contained in Paragraph 71.

72. Defendants deny the allegations contained in Paragraph 72.

73. Defendants deny the allegations contained in Paragraph 73.

74. Defendants deny the allegations contained in Paragraph 74.

75. Paragraph 75 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 75.

76. Defendants deny the allegations contained in Paragraph 76.

77. Defendants deny the allegations contained in Paragraph 77.

78. Defendants deny the allegations contained in Paragraph 78.

1 79. Defendants deny the allegations contained in Paragraph 79.

2 **SEVENTH CAUSE OF ACTION**

3 **FRAUD: CONCEALMENT, SUPPRESSION OR**

4 **OMISSION OF MATERIAL FACTS**

5 80. Defendants hereby incorporate their responses to the allegations  
6 contained in Paragraphs 1 through 79 as if set forth fully herein.

7 81. Defendants deny the allegations contained in Paragraph 81.

8 82. Defendants deny the allegations contained in Paragraph 82.

9 83. Defendants deny the allegations contained in Paragraph 83.

10 **EIGHTH CAUSE OF ACTION**

11 **BREACH OF EXPRESS WARRANTY**

12 84. Defendants hereby incorporate their responses to the allegations  
13 contained in Paragraphs 1 through 83 as if set forth fully herein.

14 85. Paragraph 85 contains legal conclusions to which no response is  
15 required. To the extent a response is deemed to be required, Defendants admit that  
16 Omniscan™ is approved by the FDA as reasonably safe for its approved uses when  
17 utilized properly, in conjunction with the medical judgment of a trained healthcare  
18 professional and in accordance with its accompanying warnings, instructions, and  
19 contraindications. Except as admitted, Defendants deny the allegations contained  
20 in Paragraph 85.

21 86. Defendants deny the allegations contained in Paragraph 86.

22 87. Defendants deny the allegations contained in Paragraph 87.

23 **NINTH CAUSE OF ACTION**

24 **BREACH OF IMPLIED WARRANTY**

25 88. Defendants hereby incorporate their responses to the allegations  
26 contained in Paragraphs 1 through 87 as if set forth fully herein.

27 89. Paragraph 89 contains legal conclusions to which no response is  
28 required. To the extent a response is deemed to be required, Defendants admit that

1 Omniscan™ is approved by the FDA as reasonably safe for its approved uses when  
2 utilized properly, in conjunction with the medical judgment of a trained healthcare  
3 professional and in accordance with its accompanying warnings, instructions, and  
4 contraindications. Except as admitted, Defendants deny the allegations contained  
5 in Paragraph 89.

6 90. Defendants deny the allegations contained in Paragraph 90.

7 91. Defendants deny the allegations contained in Paragraph 91.

8 92. Defendants deny the allegations contained in Paragraph 92.

9 **TENTH CAUSE OF ACTION**

10 **LOSS OF CONSORTIUM**

11 93. Defendants hereby incorporate their responses to the allegations  
12 contained in Paragraphs 1 through 92 as if set forth fully herein.

13 94. Defendants are without knowledge or information sufficient to form a  
14 belief as to the truth of the allegations contained in Paragraph 94 and therefore deny  
15 the same.

16 95. Defendants deny the allegations contained in Paragraph 95.

17 **RELIEF REQUESTED**

18 Defendants deny that Plaintiffs are entitled to any of the relief requested.

19 Defendants deny each and every statement, allegation, and averment  
20 contained in the Complaint that has not been expressly admitted above.

21 **AFFIRMATIVE DEFENSES**

22 Discovery and investigation may reveal that one or more of the following  
23 additional defenses are available to Defendants in this matter. Defendants  
24 accordingly assert the following defenses. Upon completion of discovery, if the  
25 facts warrant, Defendants may withdraw any of these defenses as may be  
26 appropriate. Defendants further reserve the right to amend this Answer to assert  
27 additional defenses and other claims as discovery proceeds. Further answering, and  
28 by way of additional defense, Defendants state as follows:

1 **FIRST AFFIRMATIVE DEFENSE**

2 The Complaint fails to state facts sufficient to constitute a cause of action  
3 and otherwise fails to state a claim upon which relief may be granted.

4 **SECOND AFFIRMATIVE DEFENSE**

5 Plaintiffs' claims are barred, in whole or in part, by the applicable statute of  
6 limitations, including but not limited to Cal. Code of Civil Procedure former § 340,  
7 subd. 3, or in the alternative, Cal. Code of Civil Procedure §§ 335.1, 340.5, 340.8  
8 and/or 343.

9 **THIRD AFFIRMATIVE DEFENSE**

10 If Plaintiffs sustained the injuries or incurred the expenses as alleged, and if  
11 Plaintiff William Paschal was administered Omniscan™, both of which are  
12 expressly denied, said injuries or expenses were caused by the unforeseeable  
13 alteration, improper handling, or other unforeseeable misuse of the Omniscan™ by  
14 people not within Defendants' control, including but not limited to Plaintiffs or  
15 their healthcare providers' failure to follow warnings and/or failure to follow  
16 instructions, and if the Omniscan™ had not been subjected to use in such an  
17 improper and unintended manner, Plaintiffs' damages would have been avoided.

18 **FOURTH AFFIRMATIVE DEFENSE**

19 Defendants specifically plead all defenses under the California Commercial  
20 Code now existing or which may arise in the future including, but not limited to,  
21 the defense that Plaintiffs' claims of breach of warranty, express or implied, are  
22 barred by the applicable provisions of the California Commercial Code.

23 **FIFTH AFFIRMATIVE DEFENSE**

24 Plaintiffs' claims are barred because the Omniscan™, if used, was neither  
25 defective nor unreasonably safe, and was reasonably fit for its intended use. The  
26 warnings and instructions accompanying the product at issue at the time of the  
27 occurrence or injuries alleged by Plaintiffs were legally adequate warnings and  
28 instructions.

1 **SIXTH AFFIRMATIVE DEFENSE**

2 Defendants owed no duty to Plaintiffs, and in any event, violated no duty  
3 that it may have owed to Plaintiffs.

4 **SEVENTH AFFIRMATIVE DEFENSE**

5 Plaintiffs' treating physicians and health care providers stood in the position  
6 of a learned intermediary between Defendants and Plaintiffs. Any warnings that  
7 Defendants gave were transmitted to the prescribing physicians and/or health-care  
8 providers. Defendants' only obligation is to warn the prescribing physician and/or  
9 health-care providers and said obligation was fulfilled. Plaintiffs' claims against  
10 Defendants accordingly are barred in whole or in part by the learned intermediary  
11 doctrine and/or sophisticated user.

12 **EIGHTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' claims are barred in whole or in part by the doctrines of laches,  
14 waiver and estoppel.

15 **NINTH AFFIRMATIVE DEFENSE**

16 Any and all injuries suffered by Plaintiffs, the fact of which is expressly  
17 denied by Defendants, were the direct and proximate result of sensitivities, medical  
18 conditions, reactions and/or idiosyncrasies peculiar to Plaintiff William Paschal  
19 that were unknown, unknowable or not reasonably foreseeable to these  
20 Defendants, and not as a direct and proximate result of wrongful conduct on the  
21 part of the Defendants, the fact of which is expressly denied by the Defendants.

22 **TENTH AFFIRMATIVE DEFENSE**

23 No act or omission of these Defendants was a substantial factor in bringing  
24 about the alleged injuries of Plaintiffs, nor was any such act or omission a  
25 contributing cause thereof, and any alleged acts or omissions of these Defendants  
26 were superseded by the acts or omissions of others, including Plaintiffs, which  
27 were the independent, intervening, unforeseeable, or superseding and proximate  
28 cause of any injury, damage or loss sustained by Plaintiffs.



**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to the Defendants in any possible future litigation.

**TWELFTH AFFIRMATIVE DEFENSE**

The manufacture, distribution and sale of the pharmaceutical product referred to in the Complaint was at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on the Defendants' alleged adherence or lack of adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. 301, et. Seq. ("FDCA"), and regulations promulgated thereunder, with the regulations promulgated by the Food and Drug Administration ("FDA") to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with the specific determinations by the FDA specifying the language that should be used in the labeling accompanying the subject pharmaceutical product.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the FDA over the subject pharmaceutical product at issue under applicable federal laws, regulations and rules.

1                                   **SIXTEENTH AFFIRMATIVE DEFENSE**

2           Plaintiffs' claims are barred in whole or in part because there is no private  
3 right of action concerning matters regulated by the FDA under applicable federal  
4 laws, regulations and rules.

5                                   **SEVENTEENTH AFFIRMATIVE DEFENSE**

6           Plaintiffs' claims are barred in whole or in part because the manufacture,  
7 labeling and sale of Omniscan™ was and is controlled by federal law, and the  
8 Defendants at all relevant times complied with applicable statutes and with the  
9 requirements of the FDA.

10                                  **EIGHTEENTH AFFIRMATIVE DEFENSE**

11           If any pharmaceutical product manufactured or sold by Defendants was  
12 involved in the incident alleged in the Complaint herein, which Defendants deny,  
13 then and in that event, said pharmaceutical product was not defective at the time  
14 that it left the control of the Defendants.

15                                  **NINETEENTH AFFIRMATIVE DEFENSE**

16           Plaintiffs' claims are barred in whole or in part because the products,  
17 methods, standards, and/or techniques used in manufacturing, designing,  
18 marketing, and/or labeling were in accordance with the state of the art at the time  
19 they were manufactured, designed, marketed, and/or labeled.

20                                  **TWENTIETH AFFIRMATIVE DEFENSE**

21           The pharmaceutical product at issue was fit and proper for its intended  
22 purpose and the utility of the subject pharmaceutical product at issue outweighs  
23 any possible risk inherent in the use of the subject pharmaceutical product.

24                                  **TWENTY-FIRST AFFIRMATIVE DEFENSE**

25           Plaintiffs' claims against Defendants are barred under § 6(c) of the  
26 Restatement (Third) of Torts: Products Liability.

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28    ///

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' strict liability claims are barred by the unavoidably dangerous product defense in Comment k to § 402A of the Restatement (Second) of Torts.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product at issue within the meaning of Comment j to § 402A of the Restatement (Second) of Torts.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under § 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because all acts or omissions, if any, by these Defendants (or their agents or representatives) were privileged or justified and any claim based thereon is barred.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Any warranties made by Defendants to Plaintiffs were disclaimed.

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1 **TWENTY-NINTH AFFIRMATIVE DEFENSE**

2 Any claim for breach of express warranty must fail because Plaintiffs failed  
3 to allege any representation about the product at issue giving rise to an express  
4 warranty.

5 **THIRTIETH AFFIRMATIVE DEFENSE**

6 Any claim for breach of implied warranty fails because the product at issue  
7 was used for its ordinary purpose.

8 **THIRTY-FIRST AFFIRMATIVE DEFENSE**

9 Plaintiffs' breach of warranty claims are barred because there is a lack of  
10 privity between Plaintiffs and Defendants. Moreover, Plaintiffs failed to notify  
11 Defendants of any alleged breach of warranty within a reasonable time after she  
12 discovered or should have discovered any such alleged breach and is therefore  
13 barred from recovery on such claims.

14 **THIRTY-SECOND AFFIRMATIVE DEFENSE**

15 Plaintiffs' claims are barred in whole or in part because Plaintiffs failed to  
16 mitigate their damages, if any.

17 **THIRTY-THIRD AFFIRMATIVE DEFENSE**

18 Plaintiffs' claims are barred in whole or in part because Plaintiffs assumed  
19 the risk of injury, if any, associated with the use of the product.

20 **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

21 Plaintiffs' damages, if any, are not recoverable because they are legally too  
22 remote, indirect and speculative.

23 **THIRTY-FIFTH AFFIRMATIVE DEFENSE**

24 Plaintiffs' damages, if any, were the result of pre-existing medical and/or  
25 health conditions unrelated to any conduct of, or product manufactured, distributed  
26 or introduced into interstate commerce by Defendants.

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28 ///

1                   **THIRTY-SIXTH AFFIRMATIVE DEFENSE**

2           Plaintiffs' claims based on inadequate warnings are barred even if the  
3 Defendants failed to provide adequate warnings with respect to know or potential  
4 dangers or risks associated with the use of Omniscan™, which Defendants  
5 expressly deny, because physicians prescribing Omniscan™ either knew or should  
6 have known of the potential or known dangers or risks, and there is no duty to  
7 warn members of a profession against dangers known or which should be known  
8 to members of the profession.

9                   **THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

10          Plaintiffs' claims are barred in whole or in part to the extent Plaintiffs have  
11 released, settled, entered into an accord and satisfaction, or otherwise  
12 compromised their claims.

13                   **THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

14          Plaintiffs' claims are barred or reduced by Plaintiffs' contributory and/or  
15 comparative negligence and/or contributory and/or comparative fault.

16                   **THIRTY-NINTH AFFIRMATIVE DEFENSE**

17          Plaintiffs have failed to allege fraud and/or deceit with particularity.

18                   **FORTIETH AFFIRMATIVE DEFENSE**

19          To the extent Plaintiffs' claims relate to Defendants' advertising, marketing,  
20 public statements, lobbying, or other activities protected by the First Amendment  
21 to the United States Constitution and the California Constitution, such claims are  
22 barred.

23                   **FORTY-FIRST AFFIRMATIVE DEFENSE**

24          Plaintiffs' claims and recovery are barred, reduced and/or limited pursuant  
25 to applicable constitutional, statutory and common law regarding limitations of  
26 awards and recovery.

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**FORTY-SECOND AFFIRMATIVE DEFENSE**

Defendants' liability, if any, for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to Plaintiffs' total non-economic loss, if any, including those over whom Plaintiffs could have obtained personal jurisdiction with due diligence.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have indemnified, or will in the future, with reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation or employee benefit program.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' non-economic loss must be allocated in accordance with the provision of Cal. Civil Code § 1431.1 ("Proposition 51").

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

Defendants deny any conduct for which punitive or exemplary damages could or should be awarded and deny that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims seeking punitive or exemplary damages violate the substantive and procedural aspects of the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, the Equal Protection Clause, the Excessive Fines Clause, the Commerce Clause and the cognate provisions of the California Constitution.



**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 134 L.Ed. 2d 809, 116 S.Ct. 1589 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Phillip Morris USA v. Williams*, 127 S.Ct. 1057 (2007).

**FORTY-NINTH AFFIRMATIVE DEFENSE**

No act or alleged omission of Defendants was vile, base, willful, malicious, wanton, oppressive or fraudulent, or done with a conscious disregard for the health, safety and rights of Plaintiffs and others, or with actual malice, fraud or oppression as defined in Cal. Civil Code § 3294, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Defendants assert any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

**FIFTIETH AFFIRMATIVE DEFENSE**

Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have indemnified, or will in the future, with reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation or employee benefit program.

**FIFTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' strict liability design defect claims are barred as a matter of law as set forth in *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.

**FIFTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' strict liability (failure to adequately test) claims are barred as a matter of law as set forth in *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.

**FIFTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs have failed to allege negligent misrepresentation with particularity.

**FIFTY-FOURTH AFFIRMATIVE DEFENSE**

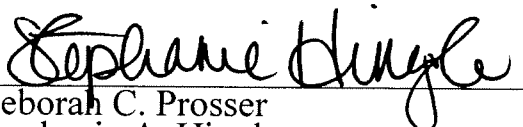
Plaintiffs have failed to allege fraudulent concealment and/or omission with particularity.

WHEREFORE, Defendants General Electric Company and GE Healthcare Inc. pray as follows:

1. That Plaintiffs take nothing by way of their Complaint;
2. That judgment be entered in favor of Defendants;
3. That Defendants be awarded their costs of suit;
4. That Defendants be awarded their attorneys' fees incurred herein; and
5. For such other and further relief as the Court deems appropriate.

Dated: March 25, 2008

KUTAK ROCK LLP

By:   
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Stephanie A. Hingle  
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GENERAL ELECTRIC COMPANY  
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